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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/768,566
Filing Date: January 29, 2004
Appellant(s): CHADA ET AL.

Gary J. Gershik
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/13/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Xu et al., U.S. Patent Publication No. 2003/0143610 A1, Published on July 31, 2003.

Office Action issued May 16, 2006 in connection with U.S. No. 10/338,604.

Statement where Xu et al and the Office Action issued May 16, 2006 in connection with U.S. No. 10/338,604 were entered.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 8, 9 and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Xu et al. (US 2003/0143610 A1 published on July 31, 2003).

Claims 1, 8, 9 and 17-19 are drawn to a method of reducing the amount or level of adipose tissue in a subject comprising administering to the subject an amount of an sFRP-5 peptide effective to reduce the amount of adipose tissue, or an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject, wherein the sFRP-5 peptide comprises consecutive amino acids having the sequence set forth in SEQ ID NO: 1 (claims 1 and 17), wherein the subject is human (claims 2 and 18), and wherein the administration is parenteral, intradermal, transdermal, transmucosal, rectal, subcutaneous, or by inhalation (claims 9 and 19).

Xu et al teach administering a polypeptide SARP3 of SEQ ID NO: 2 to a subject having a metabolic disorder characterized by aberrant SAPR3 polypeptide activity or aberrant SARP3 nucleic acid expression, e.g., obesity, diabetes, anorexia or cachexia, wherein a SARP3 modulator is a SARP3 polypeptide comprising the amino acid sequence of SEQ ID NO: 2 [0018]. Xu et al teach that the metabolic disorders include, but not limited to, obesity, diabetes, overweight, insulin resistance, anorexia, and cachexia (abstract). The polypeptide SARP3 is the exact same polypeptide as the polypeptide of SEQ ID NO: 1 of the instant invention. Though, Xu et al do not explicitly teach an amount of the polypeptide SARP3 effective to reduce the amount of adipose tissue or an amount effective to stimulate expression of the sFRP-5, the administration of the polypeptide SARP3 of amino acid sequence of SEQ ID NO: 2 would achieve the same effect in a subject as being instantly claimed. Thus, since the product of the prior art has the same chemical structure as that described in the specification, it can be assumed that the product will inherently perform the claimed process. (See MPEP 2112.02).

(10) Response to Argument

Claim Rejections - 35 USC § 102

(i) Appellants' argue that Xu et al does not teach all the elements of the claimed invention. Appellants argue that Xu et al does not teach administering (i) an amount of an sFRP-5 peptide effective to reduce the amount of adipose tissue, or (ii) an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in a subject which is

required for claims 1, 8 and 9. Appellants argue that Xu et al does not teach whether the "modulator" should inhibit sFRP-5 or induce sFRP-5 or activate sFRP-5 production. Further, Appellants argue that the Examiner only interprets the term "modulator" only either to stimulate or to inhibit.

Appellants' arguments have been fully considered but they not deemed persuasive because Xu et al contemplate treating a subject having a metabolic disorder characterized by aberrant SAPR3 polypeptide activity or aberrant SARP3 nucleic acid expression, e.g., obesity, diabetes, anorexia or cachexia, wherein a SARP3 modulator is a SARP3 polypeptide comprising the amino acid sequence of SEQ ID NO: 2 [0018]. Appellants' arguments that the term "modulate" as used by Xu et al, can be interpreted in more than two ways (i.e., stimulate or inhibit) is persuasive but Xu et al clearly state that a modulator being "SARP3 polypeptide". Further, Appellants agree on record (page 13 of Appeal Brief) that SARP3 is the same as sFRP-5. Therefore, Xu et al teach administering the same protein as being instantly claimed to treat a subject having an aberrant SARP3 polypeptide activity or aberrant SARP3 nucleic acid expression e.g., in diabetes or obesity. Since claims are not drawn to degree of reduction in the amount of adipose tissue, any administration of SARP3 polypeptide would inherently meet the claim limitation.

(ii) Appellants argue that an anticipation rejection based on inherency requires missing descriptive material to be necessarily present in the matter described in the prior art reference. Appellants argue that "the fact that a certain result or characteristic

may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Appellants argue that because Xu et al does not teach actual administration of the "modulator" nothing can occur in Xu et al., either literally or inherently.

Appellants' arguments have been fully considered but they are not deemed persuasive because Xu et al teach administering the same protein (SARP3) as a modulator to treat a subject having an aberrant SARP3 polypeptide activity or aberrant SARP3 nucleic acid expression e.g., in diabetes or obesity[0018]. Appellants agree that the SARP3 of Xu et al is the same as sFRP-5. Thus, even though Xu et al do not define "modulation", as argued by Appellants, the reference Xu et al does teach administering SARP3. Therefore, regardless of the fact that "modulate" is not defined, the fact that Xu's administration of SARP3 meets the limitation of reducing the amount of adipose tissue since this is an inherent property of SARP3. Appellants' arguments that Xu et al does not disclose an example where they administer a modulator of the polypeptide SARP3 is persuasive, but Xu et al contemplate using a modulator of SARP3 for treating a subject having an aberrant SARP3 polypeptide activity or aberrant SARP3 nucleic acid expression. Further, the demonstration of an example with the same compound/protein in the prior art is not an absolute essential for a rejection under 35 U.S.C. 102.

(iii) Appellants argue that the anticipation rejection relying on inherency is not proper unless "the missing descriptive matter is not necessarily present in Xu et al." Appellants

argue that Xu et al does not teach "an amount effective to reduce the amount of adipose or an amount effective to stimulate expression of the sFRP-5 peptide" in the subject (claims 1, 8 and 9). Similarly, for claims 18 and 19, Appellants argue that Xu et al also does not teach an amount effective to reduce the level of adipocyte formation or an amount effective to stimulate expression of the sFRP-5 peptide in the subject. Appellants argue that the Examiner has relied on a guess in a patent application and not based on an experiment as Xu et al does not teach actual administration of the "modulator".

Appellants' arguments have been fully considered but they not deemed persuasive because Xu et al disclose that an appropriate dose of a molecule will vary on the size and sample being treated and further on the route being administered and that it is within the ken of the ordinary skilled physician, veterinarian or researcher [0135]. Xu et al teach that the exemplary doses may include milligram or microgram amounts per kilogram of subject or sample weight [0136]. Xu et al emphasize that a dose would depend on many factors including the degree of expression or activity to be modulated [0136].

(iv) Appellants argue that the reference Xu et al is not an enabling disclosure for the allegedly anticipatory subject matter. Appellants argue that [0018] Xu et al is insufficient to describe the instantly claimed invention. Appellants argue that the instant invention is based on the appellants' discovery of reduction in weight in two of the three independent lines of sFRP-5 transgenic mice, which is not described by Xu et al.

Further, appellants argue that the same Examiner has acknowledged that the disclosure of Xu et al is not enabling "for a method of modulating a SARP3 mediated lipid metabolism" in connection with U.S. No. 10/338,604 (the Office Action of 5/16/2006; presented as Exhibit B.2). Appellants make a note that page 9 of the Office Action of 5/16/2006 (U.S. 10/338,604) states that on the basis of Xu et al, "a method of modulating a SARP3 mediated lipid metabolism" would require undue experimentation. Appellants cite court case Elan Pharmaceuticals, Inc. v. Mayo Foundation, 346 F.3d 1051, 1054 (Fed. Cir. 2003) and argue that a reference is enabling "if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985). Appellants cite Rockwell Intern. Corp v. U.S., 147 F. 3d 1358, 1364 (Fed. Cir. 1998) and argue that courts have refused to find anticipation based on prior art that is not enabling.

Appellants' arguments have been fully considered but they are deemed not persuasive because Xu et al in [0018] teach treating a subject having a metabolic disorder characterized by aberrant SAPR3 polypeptide activity or aberrant SARP3 nucleic acid expression, e.g., obesity, diabetes, anorexia or cachexia, by administering a SARP3 modulator, wherein a SARP3 modulator is a SARP3 polypeptide comprising the amino acid sequence of SEQ ID NO: 2 [0018]. Appellants agree that the SARP3 of Xu et al is the same as sFRP-5. Therefore, Xu et al contemplate administering the same protein as being instantly claimed to treat a subject having an aberrant SARP3 polypeptide activity or aberrant SARP3 nucleic acid expression e.g., in diabetes or

obesity. Appellants' arguments that the same Examiner finds the disclosure of Xu et al not enabling is acknowledged, but the scope of claims 9-11 in U.S. 10/338,604 is different than the invention being claimed in the instant application. Further, in the Office Action of 5/16/2006 in U.S. 10/338,604; Xu et al did not file a response back against the office action, and therefore, there was not a final decision that the reference Xu et al, in total, is not enabling. Xu et al contemplate using any modulator of SARP3 polypeptide (including an antisense SARP3, a SARP3 ribozyme or any small molecule) to modulate a SARP3 mediated metabolic activity which is different than the instant invention, and therefore, Appellants' arguments are not persuasive. Appellants' arguments that courts have refused to accept a prior art being anticipatory where said prior art is not enabling is fully considered and they are persuasive, but the arguments regarding the reference Xu et al being not enabling is not persuasive because Xu et al contemplate using the polypeptide SARP3 to modulate an aberrant SARP3 polypeptide activity or aberrant SARP3 nucleic acid expression and therefore, anticipate the instant invention.

For the above reasons, it is believed that the rejection should be sustained.

Respectfully submitted,

Gyan Chandra

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